K131517

Bayer HealthCare

510(k) Summary

AUG 0 2 2013

Submitter:

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MEDRAD, INC.

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Date Prepared: May 24, 2013

Device Trade Name: MEDRAD Twist & Go High Pressure Connector Tubing

Common Name: Connector Tubing / Tubing, Fluid Delivery

Classification Name: Tubing, Fluid Delivery [21 CFR 880.5440]

Product Code: FPK

Classification: Class II

Predicate Device(s): The subject device is equivalent to the following device:
MEDRAD High Pressure Connecting Tube
K810924, April 17, 1981

Device Description: The MEDRAD Twist & Go High Pressure Connector Tubing is a sterile, single-use only, disposable connector tube that is used to transfer contrast media and common flushing solutions from an automated injector syringe to an administration set during angiographic procedures.

	Automated injection systems with which the MEDRAD Twist & Go High Pressure Connector Tubing is intended to be used include the MEDRAD Mark 7 Arterion Injection System and equivalent injectors.
Intended Use:	The Twist & Go High Pressure Connector Tubing is intended to be used in the delivery of contrast media and common flushing solutions. The device is indicated for single use only with MEDRAD injectors.
Performance Data:	Bench and laboratory testing were performed to support a determination of substantial equivalence to the predicate devices. Results from the testing provide assurance that the proposed device conforms to the requirements for its intended use. This included the following testing: • Performance • Package Integrity • System level testing with a MEDRAD automated injector

Comparison of Features in MEDRAD High Pressure Connecting Tube (Predicate) and MEDRAD Twist & Go High Pressure Connector Tubing (Proposed)

Item		Predicate Device: MEDRAD High Pressure Connecting Tube (K810924)	Proposed Device: MEDRAD Twist & Go High Pressure Connector Tube
Labeling	Intended Use	The device, intended to be used by individuals with adequate training and experience in diagnostic imaging studies, are to be used to deliver contrast media during angiographic procedures.	The *Twist & Go* High Pressure Connector Tubing is intended to be used in the delivery of contrast media and common flushing solutions with Twist & Go Syringes. The device is indicated for single use only with MEDRAD injectors.
Construction	Description	Polycarbonate hub insert molded to a PVC tube	Polycarbonate hub UV bonded to a flexible polyurethane nylon tube
	Syringe connection	Clear Polycarbonate Female Luer	Clear Polycarbonate Twist & Go Fasturn Nut
	Administration Set Connection	Clear Polycarbonate standard male luer	Clear Polycarbonate rotating male luer
	Tubing Material	Clear Polyvinyl Chloride	Clear Polyurethane and nylon
	Tubing Volumes	1.00 – 4.78 ml	1.22 – 4.33 ml
	Tubing Lengths	25-122 cm	50-150 cm
	Outer Diameter	.478 cm (.188")	.368 cm (.145")
	Inner Diameter	.224 cm (.088")	.183 cm (.072")
	Adhesive	None	UV adhesive
Packaging	Type	Pouch	Pouch
	Material	Tyvek and clear polymer film	Tyvek and clear polymer film
	Shelf Life	3 years	3 years
Biological	Biocompatibility	Compliant to applicable sections of ISO/AAMI 10993-1:2009	Compliant to applicable sections of ISO/AAMI 10993-1:2009
	Pyrogenicity	Non-pyrogenic	Non-pyrogenic fluid path
	Latex content	Not made with natural rubber latex	Not made with natural rubber latex
	Sterilization Type	Ethylene Oxide	Ethylene Oxide
	Sterilization Assurance Level (SAL)	10^{-6}	10^{-6}
Perfor-mance	Pressure Rating	1000 psi	1200 psi

Conclusion:

MEDRAD considers the MEDRAD Twist & Go High Pressure Connector Tubing to be substantially equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, fundamental scientific technology, and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 2, 2013

MEDRAD, Incorporated
Bayer Medical Care, Incorporated
C/O Ms. Lisa A. Ewing
Principal Regulatory Affairs Specialist
One Medrad Drive
INDIANOLA PA 15051

Re: K131517
Trade/Device Name: MEDRAD Twist & Go High Pressure Connector Tubing
Regulation Number: 21 CFR 880.5440
Regulation Name: Tubing, Fluid Delivery
Regulatory Class: II
Product Code: FPK
Dated: July 8, 2013
Received: July 9, 2013

Dear Ms. Ewing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K131517

Device Name: MEDRAD Twist & Go High Pressure Connector Tubing

Indications for Use:

The Twist & Go High Pressure Connector Tubing is intended to be used in the delivery of contrast media and common flushing solutions. The device is indicated for single use only with MEDRAD injectors.

Prescription Use ___X___ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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